



Unilever

June 29, 2004

Office of Nutritional Products, Labeling
and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services
5100 Paint Branch Parkway, Building CPK1
College Park, Maryland 20740-3835

RE: *Comments on the term "Net Carbohydrates," and
Additional information relating to the April 16, 2004 petition for
nutrient content claims for carbohydrates submitted by
Unilever United States, Inc.*

To Whom It May Concern:

On March 12, 2004, FDA issued a Fact Sheet on "Carbohydrates" stating that, in addition to reviewing petitions on nutrient content claims for carbohydrates, FDA "intends to provide guidance to food manufacturers on the use of the term 'net' in relation to the carbohydrate content of food." This letter provides comments on the term "net carbohydrates." We respectfully request that FDA consider these comments as it prepares guidance on the use of this term. These comments also provide additional information relevant to our April 16, 2004 petition for nutrient content claims about carbohydrates ("petition").

Summary

In summary, we strongly recommend that "net carbohydrates" be defined as *caloric* carbohydrates. Caloric carbohydrates are carbohydrates that contribute significant levels of calories to the diet, consisting primarily of sugars and starches, and excluding primarily dietary fiber and the non-caloric proportion of sugar alcohols. In addition, we recommend that, when the term "net carbohydrates" is used on food labels, additional information should be provided on labels to explain this term. A detailed discussion of these recommendations is provided below.

2004P-0298

SUP2

Unilever United States, Inc.

Lever House • 390 Park Avenue • New York, NY 10022-4698

Telephone (212) 888-1260

Discussion

Currently, the term “net carbohydrates” has different meanings in the marketplace. For example, “net carbohydrates” may be defined as:

- Carbohydrates that provide significant levels of calories;
- Carbohydrates that are readily digestible; or
- Carbohydrates that have significant effects on blood sugar levels.

Each of these definitions has a reasonable scientific basis because different types of carbohydrates can be distinguished based on their caloric contribution, digestibility, and effects on blood sugar levels. However, because the term “net carbohydrates” is primarily directed to consumers who are interested in weight control, the most relevant definition – and the one that has the broadest scientific support – is that which refers to caloric levels.

The caloric value of foods is key information for purposes of weight control. As HHS Secretary Tommy G. Thompson said when releasing the report of FDA’s Obesity Working Group, “Counting calories is critical for people trying to achieve and maintain a healthy weight.”¹ Recent publications of the National Academy of Sciences Institute of Medicine (IOM)² and a joint expert consultation of the World Health Organization (WHO) and the UN Food and Agriculture Organization (FAO),³ as well as FDA’s own “Calories Count” obesity initiative,⁴ have affirmed that the critical factor in weight control is the intake of calories.

Therefore, in order to provide useful information to consumers about how to make healthy dietary choices relating to weight control, it is necessary to distinguish between carbohydrates that contribute significant levels of calories to the diet and those that do not.

Most of the carbohydrates in the diet, consisting of sugars and starches, contribute caloric value at 4 calories per gram. However, other carbohydrates, primarily dietary fiber and sugar alcohols, contribute significantly fewer calories.

- Dietary fiber is resistant to digestion and absorption in the human small intestine and is not a meaningful source of energy. According to the IOM, the caloric

¹ FDA Press Release, March 12, 2004.

² Institute of Medicine (IOM), *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002) (“Macronutrient Report”) at 5-4.

³ Joint WHO/FAO Expert Consultation. *Diet, Nutrition and the Prevention of Chronic Diseases*. WHO Technical Report Series 916 (2003) at 63-64.

⁴ FDA, Counting Calories, Report of the Working Group on Obesity (March 12, 2004).

contribution of dietary fiber is “still unclear.”⁵ In addition, fiber has distinctive benefits and its increased consumption should be encouraged, even by those who are watching their calories.⁶

- Sugar alcohols are partially digested and absorbed in the small intestine and, though not a significant source of energy, they do contribute some energy to the diet. Individual sugar alcohols have different caloric values.⁷

Therefore, in order to provide useful information to consumers about how to make healthy dietary choices relating to weight control, it is necessary to distinguish between the types of calories (predominantly sugars and starches) that contribute significant levels of calories to the diet, and dietary fiber and the non-caloric proportion of sugar alcohols, which do not.

Accordingly, we strongly recommend that FDA define “net carbohydrates” to mean “total carbohydrates excluding dietary fiber and the non-caloric proportion of sugar alcohols.”⁸ This definition will provide the key information that consumers need about *caloric* carbohydrates in a clear and consistent manner.

This definition is consistent with the definitions for “free,” “low” and “reduced” claims proposed by our petition. If FDA adopts the nutrient content claims proposed by our petition as well as the definition of “net carbohydrates” proposed in this letter, then claims such as “free,” “low” and “reduced” could be accompanied by a declaration of “net carbohydrates” that conveys consistent quantitative information. (For example, “Low in carbohydrate; contains ___ g net carbohydrates per serving.”)

However, even if FDA does not adopt the nutrient content claims proposed by our petition, we nevertheless recommend that FDA adopt the definition of “net carbohydrates” proposed in this letter. Regardless of whether or not any nutrient content claims for carbohydrates are permitted, the key information about carbohydrates for consumers is *caloric* information, and “net carbohydrates” should refer to *caloric*

⁵ IOM Macronutrient Report at 7-8.

⁶ See the discussion of dietary fiber in chapter 7 of the IOM Macronutrient Report.

⁷ The caloric values of the principal sugar alcohols are: 0.2 calories per gram for erythritol; 1.6 for mannitol; 2.0 for isomalt; 2.0 for lactitol; 2.1 for maltitol; 2.4 for xylitol; 2.6 for sorbitol; 3.0 for hydrogenated starch hydrolysates; and 4.0 for glycerin. American Dietetic Association. Position of the American Dietetic Association: Use of Nutritive and Nonnutritive Sweeteners. *J Am Dietetic Assoc.* 2004;104:255-275.

⁸ In this letter, we focus on dietary fiber and sugar alcohols as the predominate carbohydrates in the diet that contribute significantly less than less than 4 calories per gram. However, other carbohydrates could be treated similarly to fiber and sugar alcohols if a manufacturer were to develop adequate scientific data to substantiate such an approach.

carbohydrates (that is, total carbohydrates excluding dietary fiber and the non-caloric proportion of sugar alcohols).

Finally, we recommend that FDA state in guidance that, if the term "net carbohydrates" is used on food labels, additional information should be provided on labels to assist consumers in understanding what the term means and how the quantity of "net carbohydrates" relates to the quantity of total carbohydrates declared in the Nutrition Facts box. For example, the term should be accompanied by a statement such as "Net carbohydrates (___ g) equal total carbohydrates (___ g) excluding dietary fiber (___ g) and the non-caloric proportion of sugar alcohols (___ g)." This type of explanatory information should be provided until such time as the meaning of "net carbohydrates" has become well established in the marketplace.

In conclusion, because calories are critical to consumers who rely on information about "net carbohydrates," we strongly recommend that "net carbohydrates" be defined as *caloric* carbohydrates. Additional information supporting the use of caloric carbohydrates as the basis for carbohydrate claims can be found in our petition.

Thank you for considering our comments on this important issue.

Sincerely,



Nancy L. Schnell
Deputy General Counsel –
Marketing and Regulatory

cc: Kathleen Ellwood
Shellee Anderson
ONPLDS/DNPL